VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Erythropoiesis-Stimulating Agents – Mircera Utilization Review Medical Policy
- Mircera® (methoxy polyethylene glycol-epoetin beta injection for intravenous or subcutaneous use – Vifor Pharma)

REVIEW DATE: 07/22/2020

OVERVIEW

Mircera, an erythropoiesis-stimulating agent (ESA), is indicated for the following uses:[1]
- **Anemia due to chronic kidney disease** (CKD), including adult patients on dialysis, adult patients not on dialysis, and pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.

Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life.[1] Mircera is not indicated for use:
- In the treatment of anemia due to cancer chemotherapy.
- As a substitute for red blood cell (RBC) transfusions in those who require immediate correction of anemia.

Therapy should be initiated for patients with CKD on dialysis when the Hb level is < 10.0 g/dL and if the Hb level approaches or exceeds 11.0 g/dL, reduce or interrupt the dose of Mircera.[1] Patients with CKD not on dialysis, Mircera should be initiated when the Hb is < 10.0 g/dL and other considerations apply (e.g., patient is likely to need transfusions). If the Hb exceeds 10.0 g/dL, reduce or interrupt the Mircera dose and use the lowest dose sufficient to reduce the need for RBC transfusions.

Guidelines

The Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for anemia in CKD (2012) state that for adults with CKD on dialysis ESA therapy should be used to avoid having the Hb concentration fall below 9.0 g/dL by initiating ESA therapy when the Hb is between 9.0 and 10.0 g/dL.[2] The guidelines recommend against ESA therapy for adult patients with CKD who are not on dialysis when Hb levels are ≥ 10.0 g/dL. For adult patients with CKD who are not on dialysis with Hb levels < 10.0 g/dL, the decision whether to initiate ESA therapy should be individualized based on many factors (e.g., prior response to iron therapy, the risk of needing a transfusion, presence of symptoms). In general, ESAs should not be used to maintain Hb concentrations above 11.5 g/dL in adult patients with CKD. For pediatric patients with CKD, the Hb concentration in which ESAs should be initiated in the individual patient should be considered while being aware of the potential benefits and potential harms. In all pediatric patients with CKD receiving ESA therapy, the selected Hb concentration should be in the range of 11.0 to 12.0 g/dL. Iron supplementation can improve response to ESA therapy. Baseline and periodic monitoring (e.g., iron, total iron-binding capacity, transferrin saturation, or ferritin levels) and instituting iron replacement when needed may be useful in limiting the need for ESAs, maximizing symptomatic improvement in patients, and determining the reason for failure to adequately respond to ESAs. Iron deficiency can occur following continued ESA use and, therefore, iron supplementation is required in most patients to maintain an optimal response.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Mircera in patients with conditions other than CKD who are on dialysis. The intent of this policy is to provide recommendations for uses other than anemia in patients with CKD who are on dialysis. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Mircera as well as the monitoring required for adverse events and long-term efficacy, approval requires Mircera to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mircera is recommended in those who meet the following criteria:

FDA-Approved Indications

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1. Anemia in Patients with Chronic Kidney Disease who are on Dialysis. Approve for 3 years.

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2. Anemia in Patients with Chronic Kidney Disease who are not on Dialysis. Approve for 1 year if the patient meets the following criteria (A or B):

A) Initial Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has a hemoglobin < 10.0 g/dL; AND
- **iii.** Patient meets one of the following (a or b):
  - **a)** Patient is currently receiving iron therapy; OR
  - **b)** Patient has adequate iron stores according to the prescriber; OR

B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Approve if the patient meets the following criteria (i, ii, and iii):

Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera).
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has a hemoglobin < 11.5 g/dL; AND
- **iii.** Patient meets one of the following (a or b):
  - **a)** Patient is currently receiving iron therapy; OR
  - **b)** Patient has adequate iron stores according to the prescriber.

Dosing. Approve the following dosing regimens (A or B):

A) Approve if the dose meets the following (i and ii):
- **i.** Each dose is ≤ 180 mcg; AND
- **ii.** Each dose is given no more frequently than once every 2 weeks; OR

B) Approve if the dose meets the following (i and ii):
- **i.** Each dose is ≤ 360 mcg; AND
- **ii.** Each dose is given no more frequently than once monthly.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Mircera is not recommended in the following situations:

1. **Anemia Associated with Cancer in Patients Receiving Myelosuppressive Cancer Chemotherapy.** Mircera is not indicated and not recommended for the treatment of anemia due to cancer chemotherapy.[1]

2. **To Enhance Athletic Performance.** Aranesp is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

3. **Anemia due to Acute Blood Loss.** Use of Aranesp is not appropriate in these types of situations.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Mircera® solution for injection [prescribing information]. Basking Ridge, NJ: Vifor Pharma; August 2019.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int*. 2012;2(Suppl):279-335.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/25/2018
Annual revision	The following changes were made: 1. **Anemia in CKD for Patients Who are on Dialysis:** The approval duration was changed from 6 months to 1 year. For the criteria that requires the patient have a specified Hb value, changed the wording of "adults" to "patients ≥ 18 years of age". For the criteria that requires children to have a specified Hb value, changed the wording of "children" to "patients < 18 years of age". For the criteria that addresses patients who are currently receiving an ESA, changed from citing examples of the ESA products in criteria to providing a list of ESAs in a note. The example cited that the "Mircera prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%" was deleted. Initial approval and extended approval as a separate section was removed, including criteria that required a response to therapy in for extended approval. Dosing was revised to reflect maximum doses and intervals; the route of administration was removed (see policy). The "Duration of Therapy" and "Labs/Diagnostics" sections were also deleted. 2. **Anemia in CKD for Patients Who are Not on Dialysis:** The approval duration was changed from 6 months to 1 year. For the criteria that requires the patient have a specified Hb value, changed the wording of "adults" to "patients ≥ 18 years of age". For the criteria that requires children to have a specified Hb value, changed the wording of "children" to "patients < 18 years of age". For the criteria that addresses patients who are currently receiving an ESA, changed from citing examples of the ESA products in criteria to providing a list of ESAs in a note. The example cited that the "Mircera prescribing information recommends supplemental iron therapy when serum ferritin is < 100 mcg/L or when serum transferrin saturation is < 20%" was deleted. Initial approval and extended approval as a separate section was removed, including criteria that required a response to therapy in for extended approval. Dosing was revised to reflect maximum doses; the route of administration was removed; (see policy). The "Duration of Therapy" and "Labs/Diagnostics" sections were also deleted. 3. **Waste Management for All Indications:** This section was removed from the policy.	07/24/2019
Selected revision	**Anemia in CKD for Patients Who are on Dialysis.** Existing criteria and dosing were removed. This indication is no longer a targeted indication for this policy. All requests for anemia in CKD for patients who are on dialysis changed to approve for 1 year.	9/11/2019
Selected revision	For **Anemia in Patients with Chronic Kidney Disease who are on Dialysis,** the approval duration was changed from 1 year to 3 years.	11/06/2019
Annual revision	No criteria changes.	7/22/2020